REMARKS

Applicants submit these remarks in response to the Office Action dated September 24, 2003. Claims 1-23 and 28-52 are cancelled as being in non-elected groups. Claims 24 and 27 have been amended as discussed below, and no new matter is added.

The Examiner states that the application is not in compliance with the sequence rules, 37 C.F.R. § 1.821-1.825. Applicants have amended the specification where appropriate to indicate the sequence identifiers.

Claim 24 is rejected under 35 U.S.C. § 102(e) as being anticipated by Jeffers, U.S. Patent Publication US2002/0058036 A1, published May 16, 2002. Reconsideration and withdrawal of this rejection are respectfully requested.

Jeffers disclosed a polypeptide designated FGF-CX, which allegedly has an amino acid sequence identical to the present SEQ ID NO:4. The Examiner interprets the neuroprotective activity of FGF-CX as "providing trophic support" for glial cells, which is encompassed in claim 24 as filed, as claim 24 recites "providing trophic support for cells in a patient in need thereof." Without acquiescing to the ground of rejection, applicants submit that claim 24 as amended is not subject to this ground of rejection.

Claims 24-27 are rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly is not enabling for the full scope of the claims. Reconsideration and withdrawal of this rejection are respectfully requested.

The Examiner states that claims 24-27 are enabled for a method of enhancing the survival of dopaminergic neurons. The Examiner cites the present specification as teaching that FGF-20 is brain specific, and also cites Xie (Cytokine 11:729-35, 1999) and Szebenyi (Int. Rev. Cytol. 185:45-106, 1999) as support for the conclusion that FGF isotypes, different FGF's, and splice variants thereof may have distinct actions on cells.

The Examiner cites *In re Fisher*, 166 USPQ 18 (CCPA 1970) to support the position that it would require "a substantial inventive contribution on the part of a practitioner" to practice the invention as claimed (Office Action at page 6, lines 28-30). *Fisher* related to construction of the claim that recited a potency of "at least 1" International Unit of protein. The Court stated that this was an "open-ended" recitation, and distinguished it from cases involving "predictable factors." In cases involving predictable factors, according to the Court, a single embodiment

provides broad enablement because other embodiments could be made without difficulty and their performance characterized by known scientific laws.

In re Fisher was decided in 1970. In the 33 years since then, the arts of protein synthesis, chemistry and functional assay have advanced significantly, and applicants submit that by the time the present application was filed, let alone today, assaying the effect of a protein on cell function involved routine predictable factors, governed by "known scientific laws." Only the outcome is unpredictable, and that is where experimentation enters the picture. Furthermore, such experimentation is permitted, as long as it is not undue, and the factors for determining undue experimentation are clearly described in *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988). If the present Examiner's reasoning were applied to the technology at issue in *Wands*, it would require one of skill in the art to design a monoclonal antibody from the amino acid sequence all the way up to the 3D structure, and to identify a core structure that would allow binding affinity within the claim scope. That is not the reasoning in *Wands*. Instead, *Wands* provides for the production of numerous antibody molecules of unknown amino acid sequence, but which nevertheless shared the testable functional characteristic of binding Hepatitis B surface antigen with the claimed high affinity constant.

The main issue in *Wands* was whether it was undue experimentation for one of skill to make hybridomas and screen them to determine which ones secreted antibodies within the scope of the claims. There was no expectation that all hybridomas would secrete appropriate antibodies; on the contrary, the Court clearly stated, "[p]ractitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody." (8 USPQ 2d at 1406, emphasis added.) Furthermore, an entire "experiment," according to the Court, entailed "immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics." (8 USPQ 2d at 1407.)

By analogy, the present invention entails providing a polypeptide to a patient, wherein the amino acid sequence of the functional protein is provided by the inventors. Neither *Wands* nor *Fisher* supports the Examiner's assertion that "additional characterization of FGF-20" is required to meet the limitations of the present claims. The Xie and Szebenyi references are not on point, because the claims recite a specific FGF protein, the sequence of which is provided.

(Office Action, page 7, lines 3-5.) Instead, both court decisions focus on the experimentation that might be required to determine if the candidate (in *Wands*, a hybridoma secreting antibody; in the present case, treatment of a disease or condition using a provided polypeptide) exhibits the function that brings it within the scope of the claims. As the same experimentation would be performed regardless of the actual cell type, the alleged limited number of working examples is not on point. However, without acquiescing to the ground of rejection, applicants have amended claims 24 and 27. For the foregoing reasons, reconsideration and withdrawal of the rejection are respectfully requested.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 628-7650.

Respectfully submitted,
Nobuyuki Itoh et al.
DAVIS WRIGHT TREMAINE LLP

By _____
Jane E. R. Potter
Registration No. 33,332

2600 Century Square
1501 Fourth Avenue
Seattle, WA 98101-1688
Phone: (206) 628-7650
Facsimile: (206) 628-7699

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rat FGF-9   MAPLGEVGSYF-GVCD-AVPFGNVPVL--PVDSPVLLSDHLGQSEAGGLPRGPAVTDLDHL 57
            **** ***     *          *     *       * **     *   *   *    **     * **
rat FGF-20  MAPLTEVGAFLGGLEGLGQQVGSHFLLPPAGERPPLLGERRGALE-RGARGGPGSVELAHL 60
              ***     *     *     *       *     * * ** *   *   *                ***
rat FGF-16     MAEVGGVFASLDWDLQGFSSSLGNVPLADSPGFLNERLGQIE--GKLQRGSPTDFAHL 56

            KGILRRRQLYCRTGFMLEIFPNGTIQGTRKDHSRFGILEFISIAVGLVSIRGVDSGLYLG 117
             ***************** * * *   **** *** ******** ******************
            HGILRRRQLYCRTGFMLQILPDGSVQGTRQDHSLFGILEFISVAVGLVSIRGVDSGLYLG 120
             ***************** * * * * *** *** ******** **** ************
            KGILRRRQLYCRTGFHLEIFPNGTVHGTRHDHSRFGILEFISLAVGLISIRGVDSGLYLG 116

            MNEKGELYGSEKLTQECVFREQFEENWYNTYSSNLYKHVDTGRRYYVALNKDGTPREGTR 177
            ** ************ ** ***************** *** ****** ********** * *
            MNGKGELYGSEKLTSFCIFREQFEENWYNTYSSNIYKHGDTGRRYFVALNKDGTPRDGAR 180
            **   *** ** *** ** ************* *   *** *   * * ******* ** * *
            MNERGELFGSKKLTRECVFREQFEENWYNTYASTLYKHSDSERQYYVALNKDGSPREGYR 176

            TKRHQKFTHFLPRPVDPDKVPELYKDILSQS   208 SEQ ID NO:16
             ***************  ******* *
            SKRHQKFTHFLPRPVDPERVPELYKDLLVYTG  212 SEQ ID NO:2
             ***************    *     **  *
            TKRHQKFTHFLPRPVDPSKLPSMSRDLFRYR   207 SEQ ID NO:17
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Figure 1